SEPTAL CLOSURE DEVICES

Cross-Reference to Related Application

This application claims priority from provisional serial no. 60/431,924, filed December 9, 2002, which is incorporated herein by reference.

Background of the Invention

A patent foramen ovale (PFO) as shown in FIG. 1 is a persistent, one-way, usually flap-like opening in the wall between the right atrium 10 and left atrium 12 of the heart. Since left atrial (LA) pressure is normally higher than right atrial (RA) pressure, the flap typically stays closed. Under certain conditions, however, RA pressure can exceed LA pressure, creating the possibility for right to left shunting that can allow blood clots to enter the systemic circulation.

In utero, the foramen ovale serves as a physiologic conduit for right-to-left shunting. After birth, with the establishment of pulmonary circulation, the increased left atrial blood flow and pressure results in functional closure of the foramen ovale. This closure is typically followed by anatomical closure of the two over-lapping layers of tissue, septum primum 14 and septum secundum 16. However, a PFO has been shown to persist in a significant minority of adults.

The presence of a PFO has no therapeutic consequence in otherwise healthy adults. But patients suffering a stroke or TIA in the presence of a PFO and without another cause of ischemic stroke are considered for prophylactic medical therapy to reduce the risk of a recurrent embolic event. These patients can be treated with oral anticoagulants, but such drugs have the potential for adverse side effects such as hemorrhaging, hematoma, and interactions with other drugs. In certain cases, such as when the use of anticoagulation drugs is contraindicated, surgery may be used to suture a PFO closed. Suturing a PFO requires attachment of septum secundum to septum primum

with a stitch (continuous or interrupted), which is the common way a surgeon shuts the PFO under direct visualization.

Non-surgical closure of PFOs has become possible with umbrella devices and a variety of other similar mechanical closure designs developed initially for percutaneous closure of atrial septal defects (ASD). These devices allow patients to avoid the potential side effects often associated with anticoagulation therapies.

Summary of Embodiments of the Invention

Embodiments of the present invention are directed to devices for closing septal defects such as PFOs. The closure devices include proximal and distal occlusion members for applying compressive forces to tissue on opposite sides of septal defects to help close the defects. Material patches of a fabric or growth promoting matrix can optionally be applied to the occlusion members to cover the defect and promote tissue ingrowth to improve defect closure. The devices are collapsible for delivery and deployment, and can be easily retrieved and redeployed or repositioned if needed.

These and other features will become apparent from the following detailed description, wherein embodiments of the invention are shown and described by way of illustration. As will be realized, the invention is capable of other and different embodiments and its several details may be capable of modifications in various respects, all without departing from the invention. Accordingly, the drawings and description are to be regarded as illustrative in nature and not in a restrictive or limiting sense.

Brief Description of the Drawings

FIG. 1 is a cross-sectional view of a portion of the heart illustrating a PFO;

FIGS. 2A and 2B are perspective views of a closure device in accordance with one or more embodiments of the invention in generally collapsed and expanded states,

respectively;

FIGS. 3A – 3D are side views illustrating deployment of the closure device of FIGS. 2A and 2B in a PFO;

FIGS. 4A and 4B are perspective views of a closure device in expanded and collapsed states, respectively, in accordance with one or more further embodiments of the invention;

FIGS. 5A and 5B are perspective and side views, respectively, illustrating placement of the closure device of FIGS. 4A and 4B in a PFO; and

FIG. 6 is a side view of a closure device in accordance with one or more further embodiments of the invention.

Detailed Description

Various embodiments of the present invention are directed to methods and devices for closing septal defects such as PFOs. The devices apply compressive forces to compliant tissue on opposite sides of the defect to help close the defect.

FIGS. 2A-2B and 3A-3D generally illustrate a closure device or occluder 20 in accordance with one or more embodiments of the invention. FIGS. 2A and 2B illustrate the device 20 in collapsed and expanded states, respectively. FIGS. 3A-3D illustrate a process of deploying the device 20. The device 20 is radially collapsible into a collapsed configuration (as shown in FIG. 2A) for delivery through a catheter and deployment. Upon deployment, it expands into a predefined expanded configuration (shown generally in FIG. 2B).

The device 20 includes an expandable distal occlusion member 22 and an expandable proximal occlusion member 24 connected to each other. The distal occlusion member 22 (which can be positioned on the left atrial side of a PFO) includes a framework having a central hub 26 and a plurality of outwardly extending elongated struts 28. The free ends of struts 28 can have small loops, ball tips, or otherwise be rounded or configured to reduce trauma. The proximal occlusion member 24 (which can be placed on the right atrial side of the PFO) includes a plurality of wires in the form of loops 29, shown here as overlapping, when the device 20 is in an expanded state. As shown in FIGS. 2A and 2B, loops 29 each extend from a central hub 26 to an end cap 27. The loop forms a plane that is approximately parallel to the tissue it is closing and applies a force that is generally perpendicular to the plane (see also FIG. 5A).

In accordance with some embodiments of the invention, material patches of a fabric or growth promoting matrix can optionally be applied to the occlusion members 22, 24. When the device 20 is deployed, the patches can cover the defect and promote tissue ingrowth to improve defect closure. Numerous biocompatible materials can be used for the patches including, but not limited to, polyester fabrics (such as knitted or woven polyester fabrics), GORE-TEX® (ePTFE), and IVALON® (polyvinyl alcohol foam), naturally occurring tissue scaffolds (such as collagen or acellular tissue matrices), polyurethane, bioresorbable tissue matrices, or electrospun fabric.

The wires forming the device are preferably made of a thermally responsive material having shape memory properties (e.g., nitinol, nitinol alloys, shape memory polymeric materials). The wires could be made of a bioresorbable materials if a tissue scaffold is provided. Suitable shape memory materials can include a first, relatively pliable low temperature phase (mainly R-phase or martensite or both) and a second, relatively rigid high temperature phase (mainly austenite). Such material can, e.g., have a high temperature phase at about body temperature or, more preferably, at temperatures above about 70°F. As is generally known for such materials, the device is collapsed in the R-phase or martensite phase, and then recovers a programmed shape when body heat

causes the material in the device to transition to its austenitic phase. It should be understood that these are representative properties that can be varied.

In some respects, this device resembles a vena cava filter as shown in U.S. Patent No. 4,425,908. A vena cava filter is designed to be inserted into a major vein to prevent a blood clot from entering the lungs, a different purpose from that described here.

FIGS. 3A-3D illustrate deployment of the device 20 for closing a PFO. The device 20 can be delivered to the septal defect in the collapsed state through a standard catheter 30. The catheter 30 is passed through the defect between septum primum 14 and septum secundum 16 as shown in FIG. 3A. The distal occlusion member 22 is then deployed as shown in FIG. 3B. The catheter 30 is retrieved, and the proximal occlusion member 24 is deployed on the proximal part of the defect as shown in FIGS. 3C and 3D. Once deployed, compressive forces are applied by the device 20 to the tissue, causing septum secundum 16 to be drawn toward septum primum 14. A tissue scaffold, if provided, would cause tissue to grow around the scaffold. The device 20 remains in place while the defect can heal to close the hole.

As indicated in FIG. 3D, the struts can just contact tissue at their ends, while the loops generally contact tissue over more of the length of the loops. If desired, the device 20 can be easily retrieved and redeployed or repositioned. The device 20 can be fully or partially pulled back into the delivery sheath from the defect by pulling on end cap 27, which serves as the proximal attachment point of the occluder for use with a recovery type catheter. The device can then be removed completely from the body or redeployed.

Benefits of the device 20 include high fatigue resistance, ability to be used with small diameter delivery sheaths, reduced metal mass, ease of manufacturing, reduced cost, and overall design simplicity.

FIGS. 4A and 4B generally illustrate a closure device or occluder 30 in

accordance with one or more further embodiments of the present invention. FIG. 4A illustrates the device 30 in an expanded state when deployed, and FIG. 4B illustrates the device 30 in a generally collapsed state for delivery through a catheter.

The device 30 includes a distal occlusion member 32 (which can be positioned on the left atrial side of a PFO) and a proximal occlusion member 34 (which can be placed on the right atrial side of the PFO). When deployed, the occlusion members 32, 34 apply compressive forces to both sides of a defect, sandwiching the compliant tunnel tissue closed.

Each occlusion member 32, 34 in device 30 includes two collapsible propeller shaped wire petal members. The petals of the two occlusion members are joined by a connecting member 36, which extends into the tunnel defect when the device 30 is deployed. The loops that make up the propeller are shown extending from the central member 36 to end caps 38 and 39. These end caps, like the ones in the other embodiments, can be in a line with the connecting member 36 and can be perpendicular to septum primum and septum secundum if deployed to close a PFO; or they could be not in a line and/or could be skewed relative to a line perpendicular to septum primum and septum secundum if deployed to close a PFO

The petals collapse when the device 30 is pulled at opposite ends as shown in FIG. 4B. This collapsibility allows the device 30 to be elongated for loading into a delivery catheter. Device delivery can be achieved percutaneously by advancing the delivery catheter through the PFO defect. The device 30 can then be deployed. The device can be placed as illustrated, e.g., in FIGS. 5A-5B, with the petals generally oriented in-line with the defect. As shown, a plane defined by a loop is generally parallel to each septum and substantially perpendicular to the force applied by the loop. In FIG. 5A, the left atrial petals are illustrated generally in dashed lines and can be in the same circumferential location.

The device is preferably made from a material having shape memory properties such as Nitinol. This thermally responsive material allows the device petals to attain their desired deployed state geometry once released from the delivery catheter. The petals can be suitably sized to ensure that the device applies sufficient force to achieve defect closure.

The device 30 can close a PFO by applying compressive forces to the compliant flaps of the PFO. In accordance with some embodiments, to further promote hole closure, a fabric or a growth promoting matrix, which may include growth factors or other pharmacological agents or cells, can optionally be added to the petals to promote tissue growth over the device to plug the hole.

The petal design of the device provides wide surface contact with cardiac tissue on both the left and right atrial sides of the PFO defect. Substantial surface area contact by the petals enables generally evenly distributed pressure to be applied to close the PFO. The relatively simple structure of the device 30 allows use of an implant having a reduced metal mass. The device design also facilitates easy manufacture. The device can be made, e.g., by crimping, welding, or otherwise joining the device together in the petal geometry and then annealing.

While the FIG. 4 device 30 has two petals on each of the proximal and distal sides of the device, it should be understood that any number of petals can be used. For example, FIG. 6 illustrates a device 40 having more than two petals on each of the proximal and distal sides of the device. As shown in FIG. 6, the loops on one side are not necessarily at the same circumferential location as loops on the other side.

Having described various embodiments of the present invention, it should be apparent that modifications can be made without departing from the spirit and scope of the invention. The device is described for use with a PFO, but could be used for an atrial septal defect or a ventricular septal defect, in which case the device would

typically have a tissue scaffold or other fabric.

What is claimed: